



April 8, 1999

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Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name and address of distributor:
Pharmavite Corporation, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):
Clinically Shown to Support and Promote:
 - Joint Health, Mobility and Joint Comfort
 - Mood and Emotional Well-being

SAM-e (S-adenosylmethionine) is a naturally occurring compound found in all living organisms. In humans, SAM-e is distributed throughout the body and is involved in many important biochemical reactions. SAM-e is critical in the manufacture of joint cartilage and in the maintenance of neural cell membrane function. Because significant amounts of SAM-e are not readily available through the diet, the body is responsible for making its own SAM-e. Scientists know that certain groups of people, including the elderly, have low levels of SAM-e in their bodies. For many reasons, it is important to maintain proper levels of SAM-e in the body. Numerous clinical studies involving thousands of people indicate that supplementation with SAM-e supports and promotes the health of a multitude of body functions including:

- Joint Health, Mobility and Joint Comfort
- Mood and Emotional Well-being

SAM-e is popular in Europe where doctors have administered it for over 20 years. The benefits of SAM-e have been demonstrated by its long term use. SAM-e is now available in the U.S. mass market as a dietary supplement – only from Nature Made. Short and long term clinical studies show that SAM-e is a very safe and

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non-toxic product in levels of supplementation of up to 1,600 mg a day.

- (3) Name of the dietary ingredient if not provided in the text of the statement:
see above
- (4) Name of the dietary supplement:
SAM-e dietary supplement

The above statement(s) may be used in one or more of the following brands of products: Nature Made, Sunny Maid, Nature's Resource, AAFES, AARP, Osco, Sav-On, Valu Wise, Bartell Drug, CVS, Duane Reade, Walgreens, Longs, Spring Valley, Brite Life, Family Pharmacy, GNP, Valu-Rite.

We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,

David Kropp
Manager, Regulatory and Legal Affairs

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